K100824

510(k) Summary of Safety and Effectiveness:
Labeling Change Being Effected: Stryker Knifelight

JUN 2 5 2010

Proprietary Name:	Stryker Knifelight
Common Name:	Lighted Knife
Classification Name and Reference:	21 CFR 878.4800 Manual Surgical Instrument for General Use 21 CFR 878.4580 Surgical Lamp
Proposed Regulatory Class:	Class I (Surgical Instrument) & Class II (Surgical Lamp)
Product Codes:	79 EMF (Surgical Instrument), 79 FSQ (Surgical Lamp)
For Information contact:	Avital Merl-Margulies Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365 Fax: (201) 831-3365
Date Prepared:	June 23, 2010

Description:
The Stryker Knifelight is a sterile, single use, completely disposable ligament and tissue release knife with an integrated light source. The device is intended to provide improved visualization of tissues and ligaments inside areas with restricted view due to small incisions. During minimally open carpal ligament surgical release, this device will improve visualization of the carpal ligament, median nerve and functional ligaments and tendons. Additionally, the device has integral protective retractors which provide for additional protection of the surrounding tissue during surgery.

The Knifelight consists of two integrated components: a handpiece that acts as a power source that is connected to a blade assembly. They are sold as one device.

Indications for Use:
The Stryker Knifelight is a manual surgical instrument used for the release of the carpal tunnel ligament. It features an integrated light source to illuminate the surgical site which allows for a minimally open technique with minimal disturbance of surrounding tissue.

Proposed Modification:
The purpose of this premarket notification is to document the legal manufacturer location change and add disposal information, additional warnings & new contraindications to the package insert for the Stryker Knifelight device.

Predicate Device:
The subject Stryker Knifelight device is substantially equivalent to the predicate Stryker Knifelight device cleared under K961122.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corporation
% Ms. Avital Merl-Margulies
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

JUN 2 5 2010

Re: K100884
Trade/Device Name: The Stryker Knifelight
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FTD
Dated: March 24, 2010
Received: March 30, 2010

Dear Ms. Merl-Margulies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100884

The Stryker Knifelight is a manual surgical instrument used for the release of the carpal tunnel ligament. It features an integrated light source to illuminate the surgical site which allows for a minimally open technique with minimal disturbance of surrounding tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100884